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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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RONALD I. EISENSTEIN
100 SUMMER STREET
NIXON PEABODY LLP
BOSTON, MA 02110

EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/886,779	SABANAYAGAM ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2005* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 23-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 23-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/1/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE and the amendment filed on January 14, 2005 have been entered. The claims pending in this application are claims 11 and 23-38. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of amendment filed on January 14, 2005.

Claim Objections

2. Claim 11 is objected to because of the following informalities: "a position on the array defined by its z and y coordinates" should be "a position on the array defined by its x and y coordinates".

3. Claims 24-29 are objected to because of the following informalities: "said ordered redundant array" should be "said redundant array".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 11 and 23-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To the extent that the claimed composition/or methods are not described in the instant disclosure, claims 11 and 23-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

The recitation "there is one copy of the sequence of the 3' end of the original unextended oligonucleotide in the z dimension for each copy of the sequence of interest" is added to the claims 11, 23, and 30. However, the specification fails to define or provide any disclosure to support such claim recitation. Furthermore, in applicant's remarks filed on January 14, 2005, applicant does not indicate which part in the specification supports such claim recitation.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112,

FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 11 and 23-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 11, 23, and 30 recites the limitation "the original unextended oligonucleotide in the z dimension" in the end of the claims. There is insufficient antecedent basis for this limitation in the claim because the claims do not mention the original unextended oligonucleotide before the phrase "the original unextended oligonucleotide in the z dimension". Please clarify.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 11 and 23-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith *et al.*, (US Patent No. 5,753,439, filed on May 19, 2003).

Smith et al., teach arrays of probes. Each probe in the array comprises a constant 5'-region, a constant 3'-region and a variable internal region wherein the variable region comprised one or more repeat sequences. The repeat sequences comprise heterologous or homologous sequences which are variable in length or base sequences. Sequences contain purine or pyrimidine bases or neutral bases such as inosine. Either the nucleic acids or the probes of the array are labeled with a detectable label or fixed to a solid support. Probes are single-stranded or partly single-stranded and partly double-stranded. Arrays comprise between about 10 to about 10,000 different probes that hybridize with target nucleic acid with multiple repeats (see column 9, lines 18-34 and column 12, and Figure 5F). In certain situation, the repeat sequences are about 2 to about 2000 (see column 15, claims 1 and 2).

Regarding claims 11 and 23, since claims 11 and 23 are directed to a product (an ordered array of immobilized oligonucleotides) and are not directed to a method, the method steps recited in claims 11 and 23 which are used to make the ordered array of immobilized oligonucleotides are no patentable weight and claims 11 and 23 are product-by-process claims. Note that it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.". *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). Since claims 11 and 23 are directed an ordered array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest along the z coordinate and wherein there is

one copy of the sequence of the 3' end of the original unextended oligonucleotide in the z dimension for each copy of the sequence of interest extending in the z dimension while Smith *et al.*, teach an array comprising 10 to 10,000 different probes with 2-2000 repeats that hybridize with target nucleic acids that have the same number of or more repeats than the probes (see column 9, lines 18-34, column 12, column 15, claims 1 and 2 and Figure 5 F with the examiner's handwritings), Smith *et al.*, disclose an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide (ie., each of 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence) is attached to the array by its 5' end and comprises at least two copies of sequence of interest (ie., repeats) and wherein there is one copy of the sequence of the 3' end of the original unextended oligonucleotide (ie., target nucleic acids that have the same number of or more repeats than the probes) in the z dimension for each copy of the sequence of interest extending in the z dimension as recited in claims 11 and 23. The probes on the array taught by Smith *et al.*, are considered to be along the Z coordinate since each of these probes from one end to another end has 5' to 3' direction. Furthermore, applicant has no evidence to indicate that these probes on the array taught by Smith *et al.*, are not along the Z coordinate.

Regarding claim 30, claim 30 is directed an ordered array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest along the z coordinate and each sequence of interest is different for each extended immobilized oligonucleotide and wherein there is one copy of the sequence of the 3' end of the original unextended oligonucleotide in the z dimension for each copy of the

sequence of interest. Since Smith *et al.,* teach an array comprising 10 to 10,000 different probes with 2-2000 repeats that hybridize with target nucleic acids that have the same number of or more repeats than the probes wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence (see column 9, lines 18-34, column 12, and column 15, claims 1 and 2 and Figure 5F with the examiner's handwritings), Smith *et al.*, teach an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide (ie., each of 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence) comprises at least two copies of sequence of interest (ie., repeats) and each sequence of interest (ie., each of repeat sequences) is different and can bind to a different target nucleic acid, and wherein there is one copy of the sequence of the 3' end of the original unextended oligonucleotide (ie., target nucleic acids that have the same number of or more repeats than the probes) in the z dimension for each copy of the sequence of interest. The probes on the array taught by Smith *et al.*, are considered to be along the Z coordinate since each of these probes from one end to another end has 5' to 3' direction. Furthermore, applicant has no evidence to indicate that these probes on the array taught by Smith *et al.*, are not along the Z coordinate.

Regarding claims 24-29 and 31-33, since these different probes taught by Smith *et al.*, have 2-2000 repeats (see column 9, lines 18-34 and column 15, claims 1 and 2), claims 24-29 and 31-33 are anticipated by Smith *et al.*.

Regarding claims 34-38, different probes on the arrays in Figures 6A to 6C taught by Smith *et al.*, have 10-109 repeats wherein 5' and 3' ends of these probes are labeled with biotin

and rhodamine respectively. Target nucleic acids comprising 88, 55, and 17 repeats with a fluorescein at their 3' ends are hybridized with an identical array in separate experiments and digested with S1 nuclease. Then strand displacement assays are performed. When the probe contains more internal repeats than the target, the rhodamine label is lost in the strand displacement and the resultant product is red. Similarly, when the target contains more internal repeats than the probe, the fluorescein label is lost and the product is green. When the probe and the target both contain the same number of repeats, both rhodamine and fluorescein remain and the resultant color is yellow (see column 12, example 4, and Figures 6A to 6C). When target nucleic acids comprising 88, 55, and 17 repeats hybridize with their corresponding probes (having 88, 55, and 17 repeats) on the array, the resultant colors must be yellow. Therefore, Smith *et al.*, teach that at least two copies of a fragment of a template nucleic acid (ie., 88, 55, or 17 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeats of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claims 34 and 35, at least ten copies of a fragment of a template nucleic acid (ie., 88, 55, or 17 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeats of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claim 37, and at least fifty copies of a fragment of a template nucleic acid (ie., 88 or 55 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeat of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claim 38.

Therefore, Smith *et al.*, teach all limitations recited in claims 11 and 23-38.

Response to Arguments

In page 7, second paragraph bridging to page 9, third paragraph of applicant's remarks, applicant argues that: (1) the array of Smith *et al.*, can not be used for intended purpose of the claimed array; and (2) "The applicant's array with have repetition of its 3' end internally, while the Smith array can never have repetition of its 3' ends".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, since Smith *et al.*, teach an array comprising between about 10 to about 10,000 different probes wherein each probe has 2-2000 repeats comprising heterologous or homologous sequences which are variable in length or base sequences and is attached to the array by its 5' end (see column 9, lines 18-34 and column 12, and Figure 5F with the examiner's handwritings), the array taught by Smith *et al.*, has repetition of 3' ends of the probes. Second, claim 11 or 23 or 30 is directed an ordered array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest along the z coordinate and each sequence of interest is different for each extended immobilized oligonucleotide and wherein there is one copy of the sequence of the 3' end of the original unextended oligonucleotide in the z dimension for each copy of the sequence of interest. Applicant appears to argue that the claimed array can perform a reaction in the presence of a polymerase while the array taught by Smith *et al.*, cannot perform a reaction in the presence of a polymerase. As shown in above rejection, since Smith *et al.*, teach all structural limitations recited in claims 11 and 23-38, the array taught by Smith *et al.*, must be used in an intended purpose of the claimed array since two structural identical arrays must have same

function. Note that it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. Furthermore, applicant has no evidence to show that the array taught by Smith *et al.*, cannot be used in an intended purpose of the claimed array.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 11 and 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,284,497 B1. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but examined claims in this instant application are not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA

1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). Although independent claims 11 and 23 in this instant application are directed to an array while claim 1 of U.S. Patent No. 6,284,497 B1 is directed to a method of generating an array, claim 1 of U.S. Patent No. 6,284,497 B1 teach an array recited in claim 11 or claim 23 in this instant application since claims 11 and 23 in this instant application do not require that the original unexpected oligonucleotide is on the array. Therefore, claims 11 and 23 in this instant application are anticipated by claim 1 of U.S. Patent No. 6,284,497 B1.

Conclusion

13. No claim is allowed.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
April 28, 2005

FRANK LU
PATENT EXAMINER